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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,847	02/13/2002	Fausto Armonti	Provvisionato case 3A	8011

7590 11/19/2003

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	

ART UNIT	PAPER NUMBER
1615	13

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/074,847	Applicant(s) ARMONTI ET AL.	
	Examin r Lakshmi S Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *28-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of request for extension of time; request for examination under 37 CFR 1.114 and preliminary amendment D all dated 9-11-03 is acknowledged.

Claims 1-27 have been canceled and claims 28-40 have been presented.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-11-03 has been entered.

Claim Rejections - 35 USC § 103

1. Claims 28-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stray-Gundersen (US'723) in view of 5,292,538 to Paul et al (US '538) and EP 387 042 (EP '042).

Instant claims are directed to method of replenishing electrolyte levels lowered by passive transpiration/perspiration comprising orally administering a composition comprising sodium ion, magnesium ion, potassium ion, zinc, calcium, vitamin C, vitamin E, rutin and biotin, which is useful for heat stress, including selective restoration of the potassium and magnesium ion. Dependent claims 31 and 32 recite thermal therapy and hot mud treatment.

US '723 teaches a beverage composition comprising essential electrolytes, water, carbohydrates, antioxidants and other ingredients, as a replenishing drink to a person stressed by exercise, heat or illness (cols. 4-5, summary of the invention). US '723 teaches various amounts

of sodium chloride, potassium salts such as potassium phosphate, calcium, iron, vitamins A, B, C, E etc., in cols. 8-9 & examples I to IV in cols. 12-14. Vitamins C and E of US '723 read on antioxidants. The composition of US '723 contains sodium-230 mg/l, potassium-390 mg/l and calcium-120 mg/l. US '723 teaches 100 mg/l of Vitamin C, between 1 to 5 meq./liter magnesium ions (col. 9, lines 4-13) i.e., 24 mg to 120 mg/l and carbohydrate in the range of 1 to 2% for dextrose, by weight based on the total weight of the compositions (col. 9, lines 66-68 and col. 10, lines 1-11). US '723 further teaches preparing dry mixtures of the compositions (col. 12, lines 38-41).

US '723, discusses above, does not teach zinc, manganese, biotin, rutin and beta-carotene of the instant claims.

US '538 teaches a sustained energy composition to combat the consequences of strenuous physical exercise, trauma, malnutrition etc., comprising a blend of carbohydrates, minerals, electrolytes, vitamins such as A, B complex, C, D and E, biotin, antioxidants etc. US '538 suggests adding bioavailable forms of minerals such as magnesium, zinc, manganese, boron etc., as amino acid chelates to facilitate sustained endurance and anabolism (col. 5, lines 5 through col. 6, lines 18, see table in col. 10 through col. 11). Therefore, it would have been obvious for a skilled artisan at the time of the instant invention to add manganese, zinc, biotin and beta-carotene of US '538 in the nutritional composition of US '723, with an expectation to provide a complete nutrition with sustained energy and anabolism to a person stressed with physical exercise. The amounts of beta-carotene and biotin are mentioned in International Units and milligrams respectively, in the composition of US '538 (see example in col. 11). These amounts are different from that claimed in the instant invention. However, absent any criticality,

optimizing the amounts of beta-carotene and biotin in the composition of US '732 would have been within obvious for one of an ordinary skill in the art at the time of the instant invention because US '538 suggests that biotin and beta-carotene possess antioxidant activity required to protect against the generation of free radicals and oxidative damage (col. 7, lines 43-68).

Both US '538 and US '732 teach the addition of antioxidants in their compositions to reduce the damage caused by free radicals (col. 7, lines 12-15 of '723 and col. 7, lines 61-68 of '538). However, neither of them teaches rutin in their compositions.

EP '042 teaches rutin as an antioxidant, nutritive element and a stabilizer in various drinks, foods, beverages etc., and also as a preventive and remedy for diseases (see col. 1). EP '042 also teaches that rutin, which is also called as vitamin P, takes part in the activities of Vitamin C, causes immunopotentiation via the increase of leukocytes and thus maintains and promotes health (col. 1 and col. 10). Further, EP '042 teaches incorporating various amounts of rutin (0.01 to 5.0% w/w) (examples in col. 21-26 and col. 27, lines 1-9). In particular, EP '042 teaches rutin in the amounts of 0.01 to 2.0% w/w in foods and beverages, which is within the claimed range of 0.025 to 0.25 g/liter. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to incorporate an appropriate amount of rutin (0.01 to 2.0% w/w) of EP '042, as an antioxidant, in the beverage composition of US '723, with an expectation to reduce the damage due to oxygen free radicals, to stabilize the composition and also to maintain and promote the health of an individual who is stressed due to heat and physical exercise.

Response to Arguments

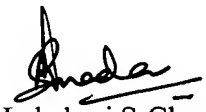
Applicant's arguments filed 9-11-03 have been fully considered but they are not persuasive.

Applicants argue that US '723 does not recognize that different electrolytes need different levels of replenishment depending on how the electrolytes were lowered or disclose all the claimed components. Applicants also argue that US '723 teaches loss of sweat during physical exercise, which is different from the lowered electrolyte during passive transpiration. Applicants' arguments are not persuasive because instant claims, other than 31 and 32, do not recite the limitation of passive transpiration, nor the claims directly relate passive transpiration to thermal stress. Accordingly, the claimed conditions 'passive transpiration" reflects a state that is in between exercise. Further, '723 teach the composition for physical exercise, as well as heat or illness. Further applicants argue that instant method of replenishing electrolytes does not use the same rehydration beverages used for sports purposes because instant passive transpiration does not use carbohydrates or glucose as an energy source. However, instant claims recite "comprising" which is open and allows for the presence of carbohydrates or other energy source. Further, applicants have not argued the other references of the instant rejection 9also made in the previous action). Therefore, the rejection is deemed proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala
Examiner
Art Unit 1615
November 17, 2003